



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

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**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

19900 MacArthur Blvd., Ste 300  
Irvine, California 92612-2445  
Telephone (949) 798-7600

**WARNING LETTER**

July 13, 2001

WL-64-01

Jane E. Davison, Proprietor  
Lance C. Griffin, General Manager  
Biomax Formulations  
10855 Sorrento Valley Road, #101  
San Diego, CA 92121

Dear Ms. Davison and Mr. Griffin:

An inspection of your facility on August 23 through September 5, 2000, found your firm to be marketing and distributing the following products: Colloidal Silver, AsthmaEnd, BioEnergy Spray, DiaBeatEze Spray, HartGard Spray, PumpUp, Pure Focus, Slumber Spray, DermaClear Spray, and BioDerm Spray. Labeling for these products contains therapeutic claims which cause the products to be drugs [section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act)]. Labeling is not limited to the immediate product containers but includes all promotional literature which you distribute in connection with your products.

Objectionable statements include the following disease claims:

Colloidal Silver	"In a world of antibiotic resistant bacteria, historic remedies may be our only hope," antibacterial antiviral substance, for existing conditions or as a preventative agent, effective against more than 650 disease causing organisms, including viruses, bacteria and fungi, disabling the enzymes used for cell metabolism of many bacteria fungi and viruses, abrasions, scrapes, eczema, acne, and open sores, warts, reduce the risk of heart disease, anthrax bacilli, B coli, B dysentery, B tuberculosis, bacillary dysentery, bladder irritation, boils, burns, wounds of the cornea, cerebro-spinal meningitis, colitis, cystitis, dermatitis, toxemia, diphtheria, ear infections, enlarged prostate, gonorrhea, impetigo, influenza, lesions, paratyphoid, pneumococci, ringworm, shingles, sprue, staphylococci, whooping cough
AsthmaEnd Spray	asthma, antihistamine, anti-inflammatory, inhibits the release of histamine, relaxes bronchial smooth muscle and prevents bronchospasm, lung cancer, emetic, expectorant, antidiarrhetic, antirheumatic, bronchodilator, antiallergic, anti-anaphylactic, arthritis, [comparisons to drugs]

isoprenaline, fenoterol, ephedrine, theophylline and phenobarbital, modulate the inflammatory cascade that leads to asthma

BioEnergy Spray	increase the synthesis of brain neurotransmitters known to correct chemical imbalances responsible for mental illness, anxiety... depression..., "Enhances the immune system by providing the metabolic burst needed to fight disease, chronic neuro-degenerative diseases, Alzheimer's, Chronic Fatigue Syndrome, Parkinson's, genetic damage related diseases include: cancer, rheumatoid arthritis, immunodeficiencies, and arteriosclerosis, degenerative disease
DiaBeatEze Spray	DiaBeatEze, corrected heart function, reduces fasting glycemia, hyperinsulinemia, hyperlipidemia, obesity, cardiovascular disease, Syndrome X, cataracts, neuropathy, chronic diseases, Type I and Type II diabetes, "significant decrease in insulin dependent diabetes" decrease in cholesterol levels, glucose tolerance was normalized, lower high blood pressure, schizophrenia and other mental illness, normalize blood glucose function, glycosuria, correct abnormalities in heart function, insulin injections were no longer required, reduces risk of cardiovascular disease and severity of some diabetic complications
HartGard Spray	heart ailments and circulatory problems, heart disease, heart muscle weakness, arrhythmia, hypertension, atherosclerosis, congestive heart failure, angina, protect against LDL cholesterol oxidation, ischemia, strokes, coronary shock, vascular insufficiency, peripheral heart disease, sore throats, thrombosis, clots, reduce blood pressure, hypertension, lung ailments, asthma, bronchitis, senility, hardening of the arteries, treatment for oxygen deprivation, [compared to drugs] trimetazidine, mepacrine, isoprenaline, and ouabain, macular degeneration, lung cancer, CHD, damage caused by cigarette smoke, reprofusion injury
Pump Up	impotence, benign prostate hyperplasia (BPH), circulatory problems
Pure Focus	macular degeneration, cataracts, eye diseases such as retinitis pigmentosa, glaucoma and myopia, inhibits abnormal platelet aggregation, arterial constriction and reduced blood flow, blood pressure normalizes, depression, headaches, inner-ear conditions, tinnitus, vertigo, insomnia, speech impairment, stroke, eyesight disorders, diabetic retinopathy
Slumber Spray	insomnia, sleep disorders, "enhance sleep...without a 'prescription drug' hangover," analgesic effects, anxiety, depression, obesity, seasonal affective disorder, migraine headaches, "sleep disorders commonly experienced by those with a genetic or personal history of alcohol addiction."

DermaClear Spay      antibacterial, antifungal, antiseborrheic, normalizes psoriatic cell reproduction, a steroid compound with antiallergic properties, psoriasis, seborrhea, eczema, dermatitis, dandruff

BioDerm Spray      Effective on all Lipid Envelope Viruses, Herpes simplex I and II, antiviral, antiseptic (which binds up herpes glyco-proteins), spermicide, antifungal, antibacterial, improves transdermal absorption

Further, labeling for Colloidal Silver, AsthmaEnd Spray, BioEnergy Spray, DiaBeatEze Spray, HartGard Spray, Pump Up, Pure Focus, Slumber Spray describes the sublingual delivery of these products as:

“WHY SUBLINGUAL OVER ORAL ADMINISTRATION...Intra-oral sublingual spray delivery systems, with 95% absorption, bypass the gastrointestinal system like intravenous. This allows nutritional molecules to enter the blood stream in seconds via highly absorbant mucosal tissue.”

Section 201(ff)(2)(A)(i) of the Act defines the term “dietary supplement” to be a product that “is intended for ingestion.” Consequently your products, which are not intended for ingestion, do not meet the definition of “dietary supplement”.

Because they are not ingested and their labeling claims that they are intended to treat, prevent, cure or mitigate disease, or are intended to affect the structure or any function of the body of man, these products are “drugs” as defined in section 201(g) of the Act and are “new drugs” [section 201(p) of the Act]. Therefore, they may not be legally marketed in this country without approved New Drug Applications [section 505(a) of the Act].

These drugs are also misbranded because their labeling fails to bear adequate directions for the conditions for which they are offered [section 502(f)(1) of the Act] and their labeling is false and misleading because it suggests that these products are safe and effective for their intended use, when in fact, this has not been established [section 502(a) of the Act].

This letter is not intended to be an all-inclusive review of all labeling and products your firm may market. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to do so may result in enforcement action being initiated by the Food & Drug Administration without further notice. The Federal Food, Drug and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

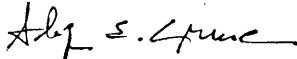
Please notify this office in writing, within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur.

If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your written reply should be addressed to:

Thomas L. Sawyer, Director, Compliance Branch  
U. S. Food and Drug Administration  
~~19900~~ MacArthur Boulevard, Suite 300  
Irvine, California 92612-2445

Sincerely,



Alonza E. Cruse  
District Director